PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

28/4

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet)
Applicant's or agent's file reference see form PCT/ISA/220	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2004/000960	21.10.2004	22.10.2003

International Patent Classification (IPC) or both national classification and IPC
A23L1/29, A23D9/00, C11C3/08, A23C11/04, A23L1/30

Applicant
ENZYMOTEC LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Groh, B Telephone No. +49 89 2399-7855

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL2004/000960

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☐ The following document has not been furnished:

   ☐ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☒ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	6-12,14
	No:	Claims	1-5,13
Inventive step (IS)	Yes:	Claims	6-12,14
	No:	Claims	1-5,13
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reference is made to the following documents:

D1: EP-A2-0 882 797 (UNILEVER N.V; UNILEVER PLC; LODERS CROKLAAN B.V) 9 December 1998 (1998-12-09)
D2: EP-A1-0 965 578 (SUNTORY LIMITED) 22 December 1999 (1999-12-22)
D3: DATABASE MEDLINE [Online] US NATIONAL LIBRARY OF MEDICINE (NLM), BETHESDA, MD, US; November 1997 (1997-11), LUCAS A ET AL: "Randomised controlled trial of a synthetic triglyceride milk formula for preterm infants." XP002315783, Database accession no. NLM9462186
D4: US-A-4 876 107 (KING ET AL) 24 October 1989 (1989-10-24)
D5: US-A-3 542 560 (RUDOLPH M. TOMARELLI et al) 24 Nov.r 1970 (1970-11-24)
D6: ANONYMOUS: "Betapol, a breakthrough in infant formula fats." in: World of Ingredients, March / April 1996, p. 41-42, XP9043320.

1. Novelty (Art. 33(2) PCT)

1.1 Novelty over enzymatically prepared OPO-triglyceride

Enzymatically prepared 1,3-oleic,2-palmitic-triglycerides (OPO-triglyceride) are known in the art.
D1 discloses enzymatically prepared OPO-triglycerides, for example as human milk fat replacers (see page 2, lines 2-3, page 3, lines 2-8, example 4 and claim 1 of D1). The OPO-triglycerides are prepared form vegetable sources.

Present claims 1-4 and 13 are not new over D1.

1.2 In view of Betapol ™ lipid

Betapol has been designed to resemble human milk fat, and is suggested to be used in infant formulas. Its fatty acid composition is shown in D3, Table 1. D6 discloses that Betapol is produced by using vegetable starting materials (see page 41, first column, bottom).

The subject matter of claims 1-5 and 13 is not new over the Betapol lipid.

1.2 Novelty of the other claims

Non of the prior art documents disclose a substitute human milk fat composition based on a lipid blend as defined in claim 6.

Although the process steps of claim 10 are known in the art, a process for the preparation of the fat base composition of any of the claims 1 to 5, has not been disclosed in the prior art.

Claims 6-12 and 14 are considered novel over the prior art.

2 Inventive step (Art. 33(3) PCT)

2.1 In view of D2

D2 is about a novel triglyceride composition, used for example in formula for premature infants and term infants, or added to milk, or blended with other oils or fats (see par. [0040]).
The lipid composition of example 4 in D2 comprises 34% palmitic acid (C16:0), which is located to 96% in the position 2 of the triglyceride (see Table 1). Linoleic acid (C16:2) is present at 15%, in a ratio of 22 : 1 (= essentially all) at the positions 1,3 of the triglycerides. The triglyceride blend is produced by esterification.

The only difference to the present application is that D2 does not specify if the source of the triglycerides is vegetable or non-vegetable.

The selection of vegetable lipids (over non-vegetable lipids) for the production of the triglycerides in D2 is considered a selection among limited alternatives, which is not sufficient to provide an inventive step over the prior art, especially since no unexpected effect has been shown, which derives from the specific choice of vegetable ingredients.

Claims 1-5 and 13 do not involve an inventive step over D2.

2.2 In view of D4

Prior art D4 discloses a substitute (human) milk fat composition for feeding young infants. The total amount of palmitic acid (see Table 3 and claim 1) is less than 33%. The amount of palmitic acid in the 2-position is more than 50%, for the blends number 1 and 4, it is 57 %.

There is no unexpected effect apparent from the small increase of the amount of palmitic acid in the 2-position of the triglycerides from 57 to 60%.

Claims 1 and 13 do not involve an inventive step over D4.

2.3 Inventive step of claim 6 and related claims

Substitute human milk fat compositions per se are known in the are (see search report). It is also known in the art to blend or add lipids with special triglyceride pattern to traditional food. See, for example claim 1 of D5, where a fat with a high content of beta-palmitic acid is blended with a milk product, in order to obtain a product, wherein the lipids resemble human milk fat.

However, there is no indication in the prior art for a substitute human milk fat composition, produced by combining an enzymatically prepared fat base as defined in claim 1 with at least one vegetable oil in the ratio defined in claim 6.

Claim 6, and the depending claims thereof are found to involve an inventive step.

3 Clarity

Claims 1-5 are defined by percentage values. For these claims is not clear what the reference unit for these relative values are: Are those percent values referring to weight-%, or number-%, or mol-% (which are all used in the prior art) ?

Claims 1-5 (and dependent claims) are not sufficiently clear to fulfill the requirement of Art. 6 PCT.

4 Industrial applicability is acknowledged in view of the given use in the filed of, for example, infant nutrition (Art. 33(4) PCT).

If new claims are filed, the description should be adapted accordingly.
In order to facilitate examination of conformity of any amendments with the requirements of Article 28 (2)41(2) PCT, the applicant is requested to clearly identify all amendments, whether there are amendments by addition, replacement, combination (e.g. of claims) or deletion.
The applicant should indicate in detail the passages in the application as filed, on which these amendments are based on (e.g. EPO Guidelines E-II, 1).